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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,137	06/28/2000	Michael E. Moseley	500.003US1	5608

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EXAMINER	
ROY, BAISAKHI	

ART UNIT	PAPER NUMBER
3737	

MAIL DATE	DELIVERY MODE
05/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/606,137	MOSELEY ET AL.	
	Examiner	Art Unit	
	Baisakhi Roy	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-7,9,11-26,29 and 54-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-7, 9, 11-26, 29, and 54-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 2/26/07 have been fully considered but they are not persuasive. With respect to the viability of cells post-implantation, Major et al. teach, as stated previously, various properties are evaluated such as graft rejection, inflammation response, and tumor formation of the transplanted cells in a patient post-transplantation (col. 4 lines 7-15). Major et al. clearly state that the transplanted cells have been shown to induce neuron migration and neurite extension demonstrating that the cells are functioning and therefore demonstrating cell viability in a patient post-transplantation. With respect to the use of MR imaging to evaluate cell properties, example 4 clearly teaches conducting an MR evaluation in a patient post-transplantation checking for tumor growth and this would necessarily also mean checking for the viability of the transplanted cells since the cells were implanted to inhibit tumor formations. Major et al. teach conducting this evaluation one month following implantation and applicant states that this MR evaluation must be done within a certain time-frame post implantation. However the claims directed to MR sensing are not limited to conducting the sensing step within a certain time frame post transplantation. The disclosure in Major et al. is directed to implantation of stem cells into patients for therapeutic purposes and checking the functionality of cells post transplantation and therefore the previous rejection is maintained and repeated below.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 5, 6, 13, 14, 17, 18, 20, 21, 25, 26, 54, 55, 57, and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Major et al. (5869463). Major et al. disclose a method for indicating viability of transplanted progenitor or stem cells grown in a culture (col. 5 lines 31-67, col. 6 lines 1-16). The method involves non-destructively observing a region of a patient to where progenitor or stem cells grown in a culture have been transplanted (col. 7 lines 33-41). The method involves sensing a property within the region of a patient that is indicative of cell viability or inviability of the transplanted progenitor or stem cells using magnetic resonance imaging (col. 11 lines 28-36) where cell viability is indicated by a property in cell chemistry resulting from an event such as cell activity/inactivity, cell growth/death, specific cell function/dysfunction, volumetric expansion of cell population, and volumetric decrease of cell population (col. 4 lines 7-14). The sensing of a property within said region of a patient that is indicative of cell viability or inviability of the implanted colony of cells is used to quantitate the cell viability (col. 4 lines 16-67). Different properties of the transplanted cells are measured and would necessarily involve monitoring tissue blood flow or changes in blood flow as vascular supply is developed and where T1 and T2 weighted images with and without

contrast agent are generated (col. 11 lines 32-36). Properties such as tissue density are measured (col. 7 lines 10-23, col. 9 lines 53-61).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 7, 9, 11, 12, 15, 16, 19, 22, 29, 56, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Major et al. in view of Morcos et al. (5497770). Major et al. disclose a method for indicating viability of transplanted progenitor or stem cells grown in a culture (col. 5 lines 31-67, col. 6 lines 1-16). The method involves non-destructively observing a region of a patient to where progenitor or stem cells grown in a culture have been transplanted (col. 7 lines 33-41). The method involves sensing a property within the region of a patient that is indicative of cell viability or inviability of the transplanted progenitor or stem cells using magnetic resonance imaging (col. 11 lines 28-36) where the system would necessarily include a volume coil surrounding the tissue and a local multi-tuned MRI RF coil. Cell viability is indicated by a property in cell chemistry resulting from an event such as cell activity/inactivity, cell growth/death, specific cell function/dysfunction, volumetric expansion of cell population, and volumetric decrease of cell population (col. 4 lines 7-14). The sensing of a property within said region of a patient that is indicative of cell viability or inviability of the implanted colony of cells is used to quantitate the cell viability (col. 4 lines 16-67).

Different properties of the transplanted cells are measured and would necessarily involve monitoring tissue blood flow or changes in blood flow as vascular supply is developed and where T1 and T2 weighted images with and without contrast agent are generated (col. 11 lines 32-36).

Major et al. teach monitoring the viability of the transplanted cells, as stated previously, but do not teach specifically monitoring one of the parameters such as lactate level, local glucose turnover, local phosphorous high-energy metabolite concentration, local F-19 labeled metabolites, alterations in tissue sodium, or changes in the conversion rates of oxygen gas to water. In the same field of endeavor Morcos et al. disclose a method for monitoring tissue viability of transplanted cells by monitoring glucose uptake (col. 9 lines 1-35). Morcos et al. teach measuring various parameters with respect to cell viability including gangrenous or necrotic tissue, muscle or connective tissue, tissues associated with atherosclerosis or clots or trauma and would necessarily involve monitoring blood flow or changes in blood flow as vascular supply is developed (col. 14 lines 57-65). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Morcos et al. to modify the teaching by Major et al. for the purpose of effectively measuring tissue viability (col. 14 lines 41-44).

5. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Major et al in view of Chenevert et al. (6567684). Major et al. disclose a method for indicating viability of transplanted progenitor or stem cells grown in a culture (col. 5 lines 31-67, col. 6 lines 1-16). The method involves non-destructively observing a region of a patient to where progenitor or stem cells grown in a culture have been transplanted (col. 7 lines

33-41). The method involves sensing a property within the region of a patient that is indicative of cell viability or inviability of the transplanted progenitor or stem cells using magnetic resonance imaging (col. 11 lines 28-36) where cell viability is indicated by a property in cell chemistry resulting from an event such as cell activity/inactivity, cell growth/death, specific cell function/dysfunction, volumetric expansion of cell population, and volumetric decrease of cell population (col. 4 lines 7-14). The sensing of a property within said region of a patient that is indicative of cell viability or inviability of the implanted colony of cells is used to quantitate the cell viability (col. 4 lines 16-67). Different properties of the transplanted cells are measured and would necessarily involve monitoring tissue blood flow or changes in blood flow as vascular supply is developed and where T1 and T2 weighted images with and without contrast agent are generated (col. 11 lines 32-36). Properties such as tissue density are measured (col. 7 lines 10-23, col. 9 lines 53-61).

Major et al. do not explicitly teach monitoring anisotropic water diffusion. In the same field of endeavor Chenevert et al. disclose method of monitoring anisotropic water diffusion of transplanted cells (col. 2 lines 10-41). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Chenevert et al. to modify the teaching by Major et al. for the purpose of determining the effectiveness of an organ or a tissue transplant (col. 3 lines 1-12).

6. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Major et al. in view of Dinsmore. Major et al. teach measuring or monitoring various parameters to determine tissue viability but do not teach measuring local concentrations of choline,

NAA, GABA, phosphocholine, or creatine. In the same field of endeavor Dinsmore disclose a method of measuring properties of transplanted cells including measuring concentration of GABA (col. 27 lines 37-54). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Dinsmore to modify the teaching by Major et al. for the purpose of effectively measuring viability of transplanted cells post-transplantation.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Baisakhi Roy whose telephone number is 571-272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BR

BR

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